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EXAMINER	
NASHED, NASHAAT T	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/803,738	BELMONT ET AL.	
	Examiner	Art Unit	
	Nashaat T. Nashed, Ph. D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-6,10,11,14-19 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-9,12,13 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/11/05 & 10/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS's: 10/17/05 &10/14/05*.

Claims 1-21 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I Claims 1-6 and 19, drawn to nucleic acid encoding the polypeptide of SEQ ID NO: 2 or fragment thereof, vector host cell and a recombinant method to make a polypeptide having an enzymatic activity, classified in Class 536, subclasses 23.2, and classified in Class 435, subclasses 195.

Group II Claims 1-6 and 19, drawn to nucleic acid encoding the polypeptide of SEQ ID NO: 4 or fragment thereof, vector host cell and a recombinant method to make a polypeptide having an enzymatic activity, classified in Class 536, subclasses 23.2, and classified in Class 435, subclasses 195.

Group III Claims 7-9, 12, 13 and 20, drawn to the polypeptide of SEQ ID NO: 2 and fragments thereof, classified in Class 435, subclass 195.

Group IV Claims 7-9, 12, 13 and 20, drawn to the polypeptide of SEQ ID NO: 4 and fragments thereof, classified in Class 435, subclass 195.

Group V Claims 10, 11 and 17, drawn to antibody raised against the polypeptide of SEQ ID NO: 2, classified in Class 530, subclass 387.1.

Group VI Claims 10, 11 and 17, drawn to antibody raised against the polypeptide of SEQ ID NO: 4, classified in Class 530, subclass 387.1.

Group VII Claim 14, drawn to a diagnostic method by determining the level of expression of the polypeptide of SEQ ID NO: 2, classified in Class 435, subclass 18.

Group VIII Claim 14, drawn to a diagnostic method by determining the level of expression of the polypeptide of SEQ ID NO: 4, classified in Class 435, subclass 18.

Group IX Claims 15, 18, and 21, drawn to a method of identifying a compound that binds to the polypeptide of SEQ ID NO: 2, classified in Class 435, subclass 18.

Group X Claims 15, 18 and 21, drawn to a method of identifying a compound that binds to the polypeptide of SEQ ID NO: 4, classified in Class 435, subclass 18.

Group XI Claim 16, drawn to a method of modulating the activity of the polypeptide of SEQ ID NO: 2 in an animal, classified in Class 514, subclass 44.

Group XII Claim 16, drawn to a method of modulating the activity of the polypeptide of SEQ ID NO: 4 in an animal, classified in Class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Group I and II, the polypeptides of Group III and IV, and the antibodies of Groups IV and V are independent chemical entities and require different searches in the patent and non-patent literature. Claims drawn to recombinant methods of making proteins using nucleic acids would be placed with the appropriate nucleic acid Group I or II because, although they have acquired a separate status in the art as shown by their different classification, they do not constitute a burden to search them in addition to the DNA sequences.

The methods of Groups VII, VIII, IX, X and XII and the nucleic acid of Group I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the methods of Groups VII, VIII, IX, X and XII do not utilize the nucleic acid of Group I.

The method of Group XI and the nucleic acid of Group I are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide of Group I can be utilized in other methods such as in a method to make a polypeptide.

The nucleic acid of Group II and the method of Groups VII, VIII, IX, X and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the polypeptide of Group II is not used in any of the methods of Groups VII, VIII, IX, X and XI.

The nucleic acid of Group II and the method of Group XII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide of Group II can be utilized in other methods such as in a method to make a polypeptide.

The polypeptide of Group III and the methods of Groups VII and IX are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of Group III can be utilized in other methods such as in a method to make antibodies.

The polypeptide of Group III, and the methods of Groups VIII, and X-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Groups VIII, and X-XII do not utilize the polypeptide of Group III.

The polypeptide of Group IV and the methods of Groups VIII and X are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of Group IV can be utilized in other methods such as in a method to make antibodies.

The polypeptide of Group IV and the methods of Groups VII, IX and XI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Groups VII, IX and XI-XII do not utilize the polypeptide of Group IV.

The antibody of Group V and the methods of Groups VII-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Groups VII-XII do not utilize the antibody of Group V.

The antibody of Group VI and the methods of Groups VII-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different

effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Groups VII-XII do not utilize the antibody of Group VI.

Inventions of Groups VII-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are independent methods having different steps and use different reagents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Emily Miao on May 15, 2006 a provisional election was made with traverse to prosecute the invention of Group III, claims 7-9, 12, 13, and 20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-6, 10, 11, 14-19, and 21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The use of the trademark such as "bluescript" page 37, line 27 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claims 7 and 9 are objected to because of the following informalities:

(a) Claims 7 and 9 depend on non-elected claims 1 and 6. For examination purposes only, all the embodiment of the embodiment of the non-elected claims were incorporated into dependent claims 7 and 9; and

(b) Claims 7-9, 12, 13, and 20 contain subject matter directed to inon-elected invention IV.

Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-9, 12, 13, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7 and 9 are directed to all polypeptide encoded by the nucleic acid of claim 1 which is directed to all nucleic acid having 80-100% sequence homology to residues 181-795 of SEQ ID NO: 1 (part d of non-elected claim 1), allelic and splice variants of parts (a)-(d) of claim 1 (part (e) of claim 1), a fragments of any of the nucleic acid of parts (a)-(e) of claim 1 having, any number of base pairs (part (f) of claim 1), any nucleic acid sequence of parts (a)-(f) containing an insertion of any number of nucleotide (part g of claim 1), any nucleic acid encoding any polypeptide that contains 1-100 amino acid substitution and/or deletion (part h of claim 1), and any nucleic acid that hybridizes under stringent condition to any of the nucleic acid of (a)-(h). Claim 8 is directed to any ortholog of SEQ ID NO: 2, which is defined as any analog of SEQ ID NO:2 from any other animal (part c of claim 8), or any allelic or splice variant of parts (a) or (c) (part d of claim 8). Finally, claim 20 is directed to any JNK-activating phosphatase protein having an amino acid terminal dual-specificity phosphoatase from any biological source. Claims 12 and 13 are included because they are dependent on claim 8.

The court of Appeals for the Federal Circuit has held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] name chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." UC California v. Eli Lilly (43 USPQ2d 1398). For claims drawn to genus, MPEP section 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Also, MPEP section 2163 states that a representative number of species mean that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. Thus, the specification fails to describe additional representative species of these polypeptides by any identifying structural characteristics or properties other than the amino acid sequence of SEQ ID NO: 2 of claim 8 part (a), or the activity cited in claim 20, for which no predictability of structure to function is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claims 7-9, 12, 13, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are broader than the enablement provided by the

disclosure with regard to the huge number of all possible Factors to be considered in determining whether undue experimentation is required, are summarized *In re* Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompasses all possible polypeptide encoded by the nucleic acid of non-elected claim 1 which is directed to all nucleic acid having 80-100% sequence homology to residues 181-795 of SEQ ID NO: 1 (part d of non-elected claim 1), allelic and splice variants of parts (a)-(d) of claim 1 (part (e) of claim 1), a fragments of any of the nucleic acid of parts (a)-(e) of claim 1 having, any number of base pairs (part (f) of claim 1), any nucleic acid sequence of parts (a)-(f) containing an insertion of any number of nucleotide (part g of claim 1), any nucleic acid encoding any polypeptide that contains 1-100 amino acid substitution and/or deletion (part h of claim 1), and any nucleic acid that hybridizes under stringent condition to any of the nucleic acid of (a)-(h). Claim 8 is directed to any ortholog of SEQ ID NO: 2, which is defined as any analog of SEQ ID NO:2 from any other animal (part c of claim 8), or any allelic or splice variant of parts (a) or (c) (part d of claim 8). Also, claim 20 is directed to any JNK-activating phosphatase protein having an amino acid terminal dual-specificity phosphoatase from any biological source. The specification provides guidance and examples in the form of an assay to clone the nucleic acid of SEQ ID NO: 1 encoding the polypeptide of SEQ ID NO: 2 from human (examples 2 and 3), its biological role in regulating JNK (example 7), and the production of the phosphatase in mammalian cell (example 8). While molecular biological techniques and genetic manipulation to make any polypeptide are known in the prior art and the skill of the artisan are well developed, knowledge regarding the genes encoding the orthologs of SEQ ID NO: 2 in all animals, the amino acid residues of SEQ ID NO: 2 required for the enzymatic activity and interaction with JNK is lacking. Thus, searching for polypeptide variants, homolog, splice variants or any mutants having insertion, deletion, substitution or combination thereof mutants is well outside the realm of routine experimentation and predictability in the art of success is extremely low. The amount of experimentation to identify a gene encoding a polypeptide or one of said variants, homolog or mutants is enormous. Since routine experimentation in the art does not include screening vast numbers of genomic, cDNA, or man-made DNA libraries, or attempt to purify the polypeptide from its natural source where the expectation of obtaining the desired polypeptide is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the amino acid residues required for the catalytic activity and interaction with JNK, the three-dimensional structure of the protein with JNK, the nucleic acid sequence encoding the various horologes, allelic variants and splice variants and method to redesign the 205 amino acid residues to change more than 100 amino acid residues of SEQ ID NO: 2 without loose of function. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 7, 9, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for rejecting the claims:

(a) Claims 7 and 9 are rejected because of their dependency on non-elected claim 1. Since they are assumed to contain all the limitation of claim 1, the claims are also considered as indefinite because of the phrases "greater than 100" and "hybridizes under stringent conditions" in claim 1 render the claim indefinite. The resulting claim does not set forth the metes and bounds of the desired patent protection.
(i) The phrase "greater than 100" is open ended and does not put a limit on the length of the amino acid or nucleic acid fragments in parts (f) and (g). The only upper limit on the fragments is the length of the nucleic acid or amino acid sequence of SEQ ID NO's: 1 and 2.
(ii) The phrase "hybridizing under stringent conditions" is indefinite because there is several sets of "stringent conditions" know in the art as low, medium and high stringent conditions and among the low, medium and high stringent conditions there are several known in the art. It is noted that applicants have exemplify some of these conditions at pages 17 and 18, but there is no exact definition of what they mean by "stringent hybridization conditions" that would satisfy the definiteness requirement under 35 USC 112, second paragraph. Inserting specific hybridization conditions in the claim would over come this rejection.

(b) The phrases "amino terminal dual-specificity phosphatase domain" and "noncatalytic carboxy-teminal domain" in claim 20 render the claim indefinite because the resulting claim does not set forth the mete and bound of the desired patent protection. The word "domain" is not defined by the specification and one of ordinary skill in the art would not know the boundary of said domain. It is not clear to this examiner where does the amino terminal domain begin and where does end for example in SEQ ID NO: 2? Similarly, the carboxyl terminal boundaries are not defined. What is the definition of non-catalytic domain? Does that mean any additional amino acid residues to the catalytic domain, even one amino acid? For examination purposes only, the claim is assumed to have no structure limitation and only functional language.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7-9 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Luche *et al.* ('124, 2005/0176124).

The '124 is a published U. S. patent application published August 11, 2005, which is a continuation in part of serial number 09/544,525, filed April 6, 2000, and 09/608,062, filed June 29, 2000, and claiming benefit to provisional application 60/142,338, filed July 2, 1999. The provisional application fully enable the amino acid sequence of SEQ ID NO: 2 of the '142 document. The earliest priority date for the instant application is September 21, 1999. Thus, the '142 publication is a qualified prior art under 35 USC 102 (e).

The '124 published application teach the nucleic acid sequence of SEQ ID NO: 1 encoding the duel-specificty phosphatase named DSP-3 of SEQ ID NO: 2. SEQ ID NO: 2 of the '124 document is 185 amino acid residues in which residues 1-169 are identical to SEQ ID NO: 2 of the instant application [claim 8, part (b), (c), and (d)]. The nucleic acid sequence of residues 1-589 of SEQ ID NO: 1 of the '124 patent document is identical to residues 98-686 of SEQ ID NO: 1 of the instant application. Thus, the nucleic acid of SEQ ID NO: 1 of the '142 document encodes a polypeptide that is more than 80% identical to the polypeptide of SEQ ID NO: 2, is expected to hybridize under any stringent hybridization condition to SEQ ID NO: 1 of the instant application, is an allelic variants of SEQ ID NO: 2, Claims 7 and 9. Also, it is considered to encode substitution/deletion mutation of 36 amino acid residues at the C-terminus. Since 169 amino acid residues at the N-terminus of SEQ ID NO: 2 of the '124 document are identical to those of SEQ ID NO: 2 of the instant application, and the two polypeptide are taught to have the same duel specificity phosphatase activity, the so called catalytic domain must be in the SEQ ID NO: 2 of the '124 document (claim 20). Applicants should note up-regulating JNK activity is an intrinsic activity of the polypeptide of SEQ ID NO: 2 of the '124 document.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Luche *et al.* ('124, 2005/0176124) in view of the prior art as exemplified by Ford *et al.* (Protein Expression and Purification 1991, 2, 95-107).

The teaching of the '124 patent document is summarized above.

Ford *et al.* is a review article teaching all available fusion partners and methods of preparing a desired protein with a fusion partner including IgG constant domain, see item 2 at page 97.

Although the '124 document teach the glutathion-S-transferase, its priority document provisional application 60/142,338 does not teach or suggest the fusion proteins and therefore, the claims were not rejected above under 35 USC 102 (e). The '124 patent document, however, provides one of ordinary skill in the art with motivation to identify modulators of duel specificity phosphatase as it teaches that the polypeptide DSP-3 may be used to identify agents that modulate DSP-3. Said agents may inhibit or enhance signal transduction *via* MAP-kinase cascade, leading to cell proliferation, see page 14, right column, paragraph 119. Thus, one of ordinary skill in the art would have been motivated at the time of invention to make large quantities of DSP-3 to screen for agent that modulates its activity. Ford *et al.* provide one of ordinary skill in the art with motivation to express protein as fusion protein as they teach their utility in the purification of a desired protein prepared by recombinant method. Thus, the ordinary skill in the art would have prepared a nucleic acid encoding DSP-3 taught in the '124 document fused to the coding sequence encoding any of the Tag polypeptide including the IgG tag and express the protein in a suitable host cell purify the protein as taught by Ford *et al.* (claims 12 and 13). Thus, the claimed invention was within the ordinary skill in the art to make and use at the time was made and was as a whole, clearly *prima facie* obvious.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTWTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen M. Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1656

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